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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/595,977 | 06/14/2007 | Mark Ashby | 1001.2219102 | 1136 |
| 28075 | 7590 | 08/03/2009 | EXAMINER | |
| CROMPTON, SEAGER & TUFTE, LLC 1221 NICOLLET AVENUE SUITE 800 MINNEAPOLIS, MN 55403-2420 | | | | MASHACK, MARK F |
| 3773 | | ART UNIT | | PAPER NUMBER |
| 08/03/2009 | | MAIL DATE | | DELIVERY MODE |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/595,977 | ASHBY ET AL. | |
| | Examiner | Art Unit | |
| | MARK MASHACK | 3773 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 24 July 2008.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1,27,40-49, 59 and 60 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1,27,40-49,59 and 60 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

This office action is in response to a communication dated 7/24/2008. Claims 1, 27, 40-49, and 59-60 have been amended.

Response to Arguments

Applicant's arguments filed 5/27/2009 have been fully considered but they are not persuasive.

Applicant argues that "severing the filament proximal of the gelatinous material would not release the anchor of Hannam". Examiner disagrees. Cutting the filament releases the device from the spring member **62** (FIG 9 and Column 12, Lines 26-31).

Applicant argues that **Hannam** does not comprise a "release mechanism". Examiner disagrees. Suture **36** couples to resilient extension member **68** to in order to position and release the plug.

Applicant argues that "the anchor of **Hannam** neither covers the puncture circumferentially... nor does it seal the punctures. Examiner disagrees. **Hannam** discloses a flexible plug **30** being able to "expand or unfold to an enlarged configuration suitable for closing off the puncture **28** generally along the artery" (Column 7, Lines 41-46) "yet is sufficiently flexible or pliable to conform generally to the shape of the interior of the artery" (Column 7, Lines 34-37).

Applicant argues that "plunger **38** does not couple a hemostatic body to the flexible disk at all". Examiner disagrees. Plunger ejects the hemostatic material into the puncture sight and into contact with the plug (FIG 10-12 and Column 13, Lines 26-31). The hemostatic body and the flexible plug would not be coupled without the plunger.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. **Claims 1** is rejected under 35 U.S.C. 102(b) as being anticipated by **Hannam et al.** (“Hannam” US 5,649,959).

Hannam discloses an apparatus comprising: a flexible plug **30** being able to “expand or unfold to an enlarged configuration suitable for closing off the puncture **28** generally along the artery” (Column 7, Lines 41-46) “yet is sufficiently flexible or pliable to conform generally to the shape of the interior of the artery” (Column 7, Lines 34-37), a hemostatic body **52**, a resilient extension element **62**, the release member comprises a suture **36** which would inherently be secured to the hemostatic body since the suture is capable of contacting the body and the body is an adhesive (Column 8, Lines 32-47).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. **Claim 27** is rejected under 35 U.S.C. 102(b) as anticipated by **Hannam** or, in the alternative, under 35 U.S.C. 103(a) as obvious over **Hannam** in view of **Haaga (US 5,254,105)**.

Regarding Claim 27, Hannam discloses all of the claimed limitations as stated above. The surface of the hemostatic material can be considered a biocompatible dissolvable capsule since it surrounds the majority of the hemostatic material. If that is not convincing, **Haaga** teaches of vascular surgical device comprising a hemostatic material being encapsulated in a biocompatible dissolvable capsule (Column 1, Line 59, - Column 2, Line 8). All of the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. Given the teachings of **Haaga**, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the hemostatic material by encapsulating it in foam. Doing so would provide a time-release mechanism to enhance the clot formation (Column 1, Lines 67, - Column 2, Line 5).

6. **Claims 40-49, and 59-60** rejected under 35 U.S.C. 103(a) as being unpatentable over **Hannam** in view of **Kensey (US 4,890,612)**.

Regarding Claim 40, element **38** couples the flexible plug to the hemostatic body and is smaller than the disk and hemostatic body diameter since they both expand once outside of the sheath.

Regarding Claims 44-49 and 59-60, the release mechanism comprises a resilient extension member **68** comprises an aperture (Column 7, Lines 37-40) and a hemostatic material (Column 7, Lines 51-54). Since the resilient extension member comprises a hemostatic material, the surface comprises a biocompatible dissolvable capsule and the center comprises a hemostatic material.

Hannam does not explicitly disclose the shape of the plug **30**. However, **Kensey** discloses a similar device which has a disk shaped anchor **52, 54** intended “to conform to the surface of the interior of the artery” and “seal the puncture when the closure is pulled into place”. Since a change in shape is an obvious modification and the anchors of **Hannam** and **Kensey** have similar intended function, it would have been obvious to modify the anchor of **Hannam** by making it in the shape of a disk. Doing so would cover/seal the puncture in the artery.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARK MASHACK whose telephone number is (571)270-3861. The examiner can normally be reached on Monday-Thursday 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mark Mashack/
Examiner, Art Unit 3773

/(Jackie) Tan-Uyen T. Ho/
Supervisory Patent Examiner, Art Unit 3773